ARL Analytical Research Laboratories	Form
Document Number: QUF-209-V1	Implementation / Revision Date: 09/14/12
Document Title: Microbiology OOS Isolation and Identification Data Form	

Check List:

- ☑ Comments Updated on Sterility/Fungal Log
- ☑ Notes Updated in LIMS
- ☑ Result Field Updated in LIMS
- ☐ Client contacted
- ☑ Investigator Notified

Date/Microbiologist Initials 10/5/12 BW

Client New England Compounding Center

ARL Number 188140

Original Observation:
large cotton like ball covered in product in SDB vial

Colonies Isolated:

- ☑ Yes-Complete this form and Proceed to OOS Investigation; Notify client and update Comments/Notes/Results
- ☐ No-Notify client and update Comments/Notes/Results

Colony Morphology:
white filamentous raised fungal colonies w/ blackish green center and top

Gram Stain Result/Cell Morphology:
NA

Species Level Identification:
NA

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ARL Analytical Research Laboratories	Form
Document Number: QUF-113-V5	Implementation / Revision Date: 09/14/12
Document Title: Microbiology Out-of-Specification Investigation	

1. Description of OOS Results:

ARL No: 188140	Date of Result: 10/05/2012
Client: New England Compounding Center	Sample Description: Methlyprednisolone AC (PF) 80 mg/mL Injection
Product Lot # 08102012@51	Microbiologist: Amar Arafat
Test performed: Fungal	Date Tested: 09/26/2012
Limit: Sterile / Not Sterile	OOS Result: Not Sterile

2. OOS Review: **Acceptable:**

Negative Control Yes☒ No☐

Environmental Monitoring Yes☒ No☐ N/A☐

Proper Test Procedure Performed Yes☒ No☐

3. Additional analysis

Type of contaminant Bacterial ☐ Fungal ☒

Gram stain of sample Isolation P ositive ☐ Negative ☐ NA

Gram stain of Environmental Isolation Positive ☐ Negative ☐ N/A☒

4. This section to be filled out by the Investigator/Management

Can this test be invalidated due to a high probability of laboratory error? Yes☐ No☑

If Yes, Why was the test invalidated and what corrective action is being taken

NA

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If No, List any notes on Investigation and Client Communications:

Client not contacted due to on going investigation

Has a report been issued with the final result and explanation of test result? Yes ☑ No ☐

Was a re-test requested by the client? Yes ☐ No ☑

Result of re-test NA

Investigator: THyde Date: 10/15/2012

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